

REMARKS

Claims 1-28 are pending. Claims 1, 3, 15, 20, and 23 have been amended. Support for the amendments made to claims 1, 3, 15, 20, and 23 may be found, *inter alia*, at pp. 8-9 of the specification, as well as Figures 1-5, of the application as filed. No new matter has been introduced. An action on the merits is respectfully requested.

In the Office Action dated September 19, 2005 (hereinafter referred to simply as the "Office Action"), the Examiner rejected:

1. Claims 1-5, 7-9, 11, 13-14, 16, and 20-22 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Application Publication No. 2002/0091357 to Trautman et al. (hereinafter referred to as "Trautman");

2. Claims 6, 23-24, and 26-27 under 35 U.S.C. § 103(a) as being unpatentable over Trautman in view of U.S. Patent No. 5,451,210 to Kramer et al. (hereinafter referred to as "Kramer");

3. Claims 15 and 28 under 35 U.S.C. § 103(a) as being unpatentable over Trautman alone, or in view of Kramer and in further view of U.S. Patent No. 5,989,229 to Chiappetta (hereinafter referred to as "Chiappetta");

4. Claims 10 and 17-19 under 35 U.S.C. § 103(a) as being unpatentable over Trautman alone, or in view of Kramer; and

5. Claims 12 and 25 under 35 U.S.C. § 103(a) as being unpatentable over Trautman alone, or in view of Kramer in further view of U.S. Patent No. 102,262 to Herrick (hereinafter referred to as "Herrick").

The above-noted rejections are respectfully traversed with respect to the claims as amended herein.

Claim 1, as amended herein, recites (emphases added):

1. An injection apparatus, comprising:
a single, unitary housing;
a group of lancets configured to move axially within the housing; and
an injection spring to drive the group of lancets out of the housing upon actuation of the injection apparatus.

In the Office Action, the Examiner asserts that Trautman discloses (*see* Office Action, page 2; emphases added):

an injection apparatus with a housing and a group of about 30-40 lancets and an injection spring to drive the lancets out of the housing upon actuation. The device also includes a push button trigger, a cap, a lancet base, at least two shear pins and four guides that are configured at quarter turns around the base of the housing. The outside of the housing is considered a finger rest. See figures 2, 4-7 and paragraphs 0035, 0037, 0053 and 0056.

Although the Examiner makes reference to certain figures and paragraphs within the cited reference, the Examiner does not specify exactly what structure within the cited portion(s) of the reference purportedly corresponds to each of the elements and/or limitations of the claims. Thus, in the following discussion, the Applicant presents arguments based on the Applicant's best assumption as to what the Examiner may be referring to.

First, with regard to (amended) claim 1 presented above, while the sections of Trautman that have been cited by the Examiner reference an "impact applicator 10" having a "body 12", it is respectfully submitted that the cited sections, as well as the remaining sections, of Trautman fail to disclose an injection apparatus having a "single, unitary housing". For example, Pars. [0035] and [0053] of Trautman provide (emphases added):

[0035] FIG. 1 illustrates a system for applying a microprotrusion member to the stratum corneum. The system includes an impact applicator 10, a retainer 34, and a microprotrusion member 44. The applicator 10 is preferably reusable while the retainer 34 and microprotrusion member 44 are preferably for one time use. As shown in FIG. 1, the retainer 34 and microprotrusion member 44 are packaged together in a preferably sterile package 100 having a removable cover 102. After removing the cover 102, a skin proximal end 13 of the applicator 10 is inserted in an open skin distal end 40 of retainer 34 in order to removably mount the retainer 34 on the applicator 10. Thus, the applicator 10 and the retainer 34 have a configuration which allows the retainer to be mounted directly onto the applicator while still in the package 100.

[0053] The applicator 10 includes a body 12 and a piston 14 movable within the body. A cap 16 is provided on the body 12 for activating the applicator to impact the stratum corneum with the microprotrusion member 44. An impact spring 20 is positioned around a post 22 of the piston 14 and biases the piston downward (i.e., towards the skin) with respect to the body 12. The piston 14 has an impact surface 18 which is substantially planar, slightly convex, or configured to match the contours of a particular body surface. The surface 18 of the piston 14 impacts the microprotrusion member 44 against the skin causing the microprotrusions 90 to pierce the stratum corneum.

Clearly, Trautman discloses a “system”, wherein the system includes an “applicator 10”, a “retainer 34”, and a “microprotrusion member 44”, and wherein the applicator has “a body 12”. Thus, if it is assumed that, in Trautman, the “system” corresponds to the claimed “injection apparatus”, then Trautman’s system does not disclose the first element of claim 1 because the “system” is made up of at least three separate structures, which must be assembled to complete the system. Thus, any “housing” that the “system” may be assumed to have is neither “single” (as the “system” must include at least an applicator “housing” and a separate retainer “housing”), nor unitary (as the aforementioned at-least-two housings must be connected to form the “system” housing).

If, on the other hand, the “applicator 10” is assumed to correspond to the claimed injection apparatus, then the “body 12” would correspond to the “housing” recited in claim 1. However, claim 1 also requires that the lancets be configured “to move axially within the housing”. But, given that, in Trautman, the microprotrusion member 44 is confined to the

retainer 34, the latter is not configured to, and does not, move axially within the housing, i.e., within the body 12. Put another way, the microprotrusion member is contained within the retainer 34 which, in turn, is connected to the applicator body 12. However, the microprotrusion member never moves, nor is it intended to move, through the body 12.

Finally, as quoted above, the Examiner also asserts that Trautman discloses “four guides that are configured at quarter turns around the base of the housing”. Given the placement of the asserted “guides” in Trautman, the Examiner’s statement would intimate that the housing is actually constituted by a portion of the retainer 34. However, if the retainer 34 is taken to correspond to the “housing” recited in claim 1, then the third element of claim 1, *inter alia*, would not be met.

More specifically, claim 1 requires that the lancets be driven out of the housing of the injection apparatus upon actuation of the apparatus. Thus, the only way in which the “housing” of the retainer 34 can be assumed to correspond to the housing recited in claim 1 is for the retainer itself to be the “injection apparatus”. As is clear from the cited reference, however, this is not the case because the retainer 34 has no actuation mechanism and, therefore, cannot be actuated on its own. Rather, an applicator 10 must be connected to the retainer 34 to create an “injection apparatus”. In short, the “housing” of the retainer cannot correspond to the “housing” recited in claim 1. Moreover, it cannot be asserted that the walls, or “housing”, of both the applicator 10 and the retainer 34, together, correspond to the claimed housing because, as noted previously, such a housing would be neither single nor unitary.

In light of the above, it is respectfully submitted that Trautman does not disclose or teach, *inter alia*, a single, unitary housing; a group of lancets configured to move axially within the

housing; and an injection spring to drive the group of lancets out of the housing upon actuation of the injection apparatus. The Applicant therefore respectfully submits that claim 1, as amended, distinguishes over the cited art and is in condition for allowance. As such, it is respectfully requested that the rejection of claim 1 be withdrawn.

In addition, claims 2-19 depend, either directly or indirectly, from claim 1. As such, and in light of the above discussion, it is respectfully submitted that claims 2-19 also distinguish over the cited art for at least the same reasons as those noted above in connection with amended claim 1. The Applicant, therefore, respectfully submits that claims 2-19 are also in condition for allowance.

Independent claim 20 has been amended herein to include the limitation discussed above in relation to claim 1, i.e., that of *a single, unitary housing*. As such, it is respectfully submitted that amended claim 20 distinguishes over Trautman for at least the same reasons as those noted above in connection with amended claim 1. The Applicant therefore respectfully requests that the rejection as to claim 20 be withdrawn, as this claim is now believed to be in condition for allowance.

In addition, claims 21-22 depend directly from claim 20. As such, it is respectfully submitted that claims 21-22 also distinguish over the cited art for at least the same reasons as those noted above in connection with amended claims 1 and 20. Therefore, the Applicant respectfully submits that claims 21-22 are also in condition for allowance.

Claim 23 was rejected over Trautman in view of Kramer. However, independent claim 23 has been amended herein to include the limitation discussed above in relation to claim 1, i.e., that of *a single, unitary housing*. As such, it is respectfully submitted that amended claim 23

distinguishes over Trautman for at least the same reasons as those noted above in connection with amended claim 1. Moreover, Kramer does not rectify the shortcomings of Trautman. As such, the references fail to disclose, teach, or suggest, either independently or in combination, all of the limitations of amended claim 23. The Applicant therefore respectfully requests that the rejection as to claim 23 be withdrawn, as this claim is now believed to be in condition for allowance.

In addition, claims 24-28 depend directly from claim 23. As such, it is respectfully submitted that claims 24-28 also distinguish over the cited art for at least the same reasons as those noted above in connection with amended claims 1 and 23. Therefore, the Applicant respectfully submits that claims 24-28 are also in condition for allowance.

As has been discussed above, Trautman, which was cited in the Office Action as the primary reference against all of the claims, does not disclose, teach, or suggest all of the claimed limitations for which it has been cited. Moreover, the additional references cited in the Office Action as bases for rejections made under 35 U.S.C. 103(a) do not rectify Trautman's shortcomings in this regard. Therefore, all of the pending claims, as amended, distinguish over the cited art. Nevertheless, the Applicant notes, by way of example, that additional, independent grounds also exist for distinguishing various of the claims over the cited art.

For example, claim 3, as amended, requires that the lancet base be in direct mechanical communication with the injection spring. In rejecting claim 3 under 35 U.S.C. 102(b) as being anticipated by Trautman, the Examiner merely asserts that Trautman discloses "an injection spring to drive the lancets out of the housing upon actuation. The device also includes . . . a lancet base . . .". See Office Action, p. 2. However, even assuming that Trautman discloses a

lancet base--again, the Examiner does not specify which structure, if any, in Trautman corresponds to the lancet base--and an injection spring, the former is not in any kind of communication, let alone direct mechanical communication, with the latter. Thus, as shown, e.g., in Figs. 4-7 of Trautman, the impact spring 20 is encased by the piston 14 (and the impact surface 18). As such, given the intermediaries of the piston 14 and impact surface 18, even if a lancet base were disclosed in Trautman, the lancet base simply cannot be in direct mechanical communication with the spring 20. Therefore, it is respectfully submitted that claims 3 distinguishes over the cited art for this additional reason, such that the rejection as to this claim should be withdrawn.

In addition, claim 4 recites (emphases added):

The injection apparatus of claim 3, further including at least one shear pin in mechanical communication with both the lancet base and the housing, wherein the at least one shear pin maintains the mechanical position of the lancet base relative to the housing until the at least one shear pin is fractured upon device actuation.

Again, the Applicant is uncertain as to what structure in Trautman the Examiner is referring to when the Examiner asserts that the device disclosed in Trautman “includes . . . at least two shear pins”. Nevertheless, the Applicant respectfully submits that there is no structure in Trautman (including the frangible sections 64) that is in contact with both a “lancet base” and the housing. In addition, there is no structure in the device of Trautman that “maintains the mechanical position of the lancet base relative to” the housing. Therefore, in addition to the grounds discussed above in connection with amended claims 1 and 3, it is respectfully submitted that claim 4 distinguishes over the cited art for this additional, independent reason. It is therefore respectfully requested that the rejection as to claim 4 be withdrawn.

In connection with claims 7 and 8, the Examiner asserts that the device disclosed in Trautman includes “four guides that are configured at quarter turns around the base of the housing.” Based on Figures 2 and 7 of Trautman, the Applicant assumes that the Examiner is referring to the “frangible sections 62”. Assuming this to be the case, it is noted that, while the frangible sections 62 certainly appear to be “configured at quarter turns around” the ring 64, they have little, if anything, to do with the “at least one guide to provide axial stability during administration of a vaccination”, as claimed in claims 7 and 8 (emphasis added). Therefore, in addition to the grounds discussed above in connection with amended claims 1 and 3, it is respectfully submitted that claims 7 and 8 distinguish over the cited art for this additional, independent reason. It is therefore respectfully requested that the rejections as to claims 7 and 8 be withdrawn.

Additionally, amended claim 15 recites “a soft matrix between the cap and the group of lancets to protect said lancets.” In rejecting this claim, the Examiner asserts that “Chiappetta discloses such a matrix for enhancing the sterility of the needle prior to use. See figures 3-4.” (See Office Action, p. 3). Figures 3 and 4 of Chiappetta disclose an “absorbent material 25”, with regard to which, Chiappetta provides as follows: “Preferably, the absorbent material 25 is cotton. However, other materials that can easily absorb liquid can be used. This allows absorbent material 25 to retain a load of drug thereon and facilitates application of the drug to the patient.” See col. 2, lines 61-65 (emphasis added); see also col. 3, lines 4-9 and col. 4, lines 1-10. Thus, by its very own terms, the asserted “soft matrix” disclosed in Chiappetta serves as a vehicle for drug delivery; it has nothing to do with “enhancing the sterility of the needle prior to use”, as asserted by the Examiner, and it certainly has nothing to do with “protecting the lancets”, as recited in claim 15. As such, in addition to the grounds discussed above in

connection with amended claim 1, it is respectfully submitted that (amended) claim 15 distinguishes over the cited art for this additional, independent reason. It is therefore respectfully requested that the rejection as to claim 15 be withdrawn.

Finally, claims 12 and 25 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Trautman alone or in view of Kramer in further view of Herrick. As an initial matter, it is respectfully submitted that the Trautman, Kramer, and Herrick references cannot properly form the basis of a 35 U.S.C. § 103(a) rejection as there is no suggestion whatsoever that the latter may be combined with the two former references. *See, e.g., In re Jones*, 958 F.2d 347, 351, 21 USPQ2d 1941, 1943-44 (Fed. Cir. 1992) (“Before the PTO may establish *prima facie* obviousness, there must be some suggestion for doing so, found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art.”). Quite simply, whereas Kramer (and, presumably,) Trautman are directed to devices that are intended for one-handed operation, the device of Herrick is clearly meant for two-handed operation, wherein one hand grabs the purported “finger rests”, and the other turns the “thumb screw D” to “move the piston-head” back and forth within the cylindrical case. *See* Herrick, col. 1, and Figures 1 and 2.

Nevertheless, even if, *arguendo*, the references could properly be combined, Herrick does not disclose, teach, or suggest the claimed “finger rests”. Rather, it discloses a structure that appears to extend around the circumference of the disclosed device, wherein the user would wrap his/her hand around the device, with the user’s thumb and index finger lying underneath the curved portion of the structure. That is, given the two-handed operation of Herrick’s device, the device has, perhaps, a “hand-grabbing section”, but certainly not one, let alone two, “finger

rests". As such, in addition to the grounds discussed above in connection with amended claims 1 and 23, it is respectfully submitted that claims 12 and 25, respectively, distinguish over the cited art for this additional, independent reason. It is therefore respectfully requested that the rejections as to claims 12 and 25 be withdrawn.

It is believed that claims 1-28, as amended herein, are in condition for allowance, and a favorable action is respectfully requested. If, for any reason, the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorneys at the Los Angeles, California telephone number (213) 488-7100 to discuss the steps necessary for placing the application in condition for allowance.

Respectfully submitted,

Date: January 18, 2006

By: 

Roger R. Wise
Registration No. 31,204
Attorney for Applicant(s)

PILLSBURY WINTHROP SHAW PITTMAN LLP
725 South Figueroa Street, Suite 2800
Los Angeles, CA 90017-5406
Telephone: (213) 488-7100
Facsimile: (213) 629-1033